CV

IN THE COURT OF COMMON PLEAS
BUTLER COUNTY, OHIO
CIVIL DIVISION

2014 08 2221

DELANA WHEATON
7654 HOPEFUL ROAD
FLORENCE, KY 41042

PLAINTIFF

v.

WEST CHESTER HOSPITAL, LLC
c/o GH&R BUSINESS SVCS., INC.
511 WALNUT STREET
1900 FIFTH THIRD CENTER
CINCINNATI, OH 45202
(Serve via Certified Mail)

And

UC HEALTH
c/o GH&R BUSINESS SVCS., INC.
511 WALNUT STREET
1900 FIFTH THIRD CENTER
CINCINNATI, OH 45202
(Serve via Certified Mail)

And

TRIHEALTH, INC.
c/o DONNA S. NIENABER, Registered Agent
619 OAK STREET
Cincinnati, OH 45206
(Serve via Certified Mail)

And

GOOD SAMARITAN HOSPITAL OF CINCINNATI
c/o DONNA S. NIENABER, Registered Agent
619 OAK STREET
Cincinnati, OH 45206
(Serve via Certified Mail)

Case No.

Judge:

COMPLAINT & JURY DEMAND
- PROFESSIONAL TORT

MOTION FOR EXTENSION OF TIME TO FILE AFFIDAVIT(S) OF MERIT ATTACHED

EXHIBIT
A

And

CENTER FOR ADVANCED SPINE TECHNOLOGIES
c/o CT CORPORATION SYSTEM
1300 EAST NINTH STEET, #1010
CLEVELAND, OHIO 44144
(Serve via Certified Mail)

And

ABUBAKAR ATIQ DURRANI, M.D.
(Served by Hague Convention)
(Serve at adurrani.yourspinedoctor@gmail.com
6905 Burlington Pike
Florence, KY 41042

And

MEDTRONIC, INC., a Minnesota Corporation,
c/o CT CORPORATION SYSTEM
1300 EAST NINTH STEET, #1010
CLEVELAND, OHIO 44144
(Serve via Certified Mail)

And

MEDTRONIC SOFAMOR DANEK USA, INC.,
a Tennessee corporation,
c/o CT CORPORATION SYSTEM
1300 EAST NINTH STEET, #1010
CLEVELAND, OHIO 44144
(Serve via Certified Mail)

And

ALPHATEC SPINE, INC.
c/o Ebun S. Garner
5818 El Camino Real
Carlsbad, CA 92008
(Serve via Certified Mail)

And

ALPHATEC HOLDINGS, INC.
c/o Corporation Service Company
2711 Centerview Rd., Suite 400
Wilmington, DE 19808
(Serve via Certified Mail)

And

PARCELL LABORATORIES, LLC
c/o United State Corporation Agents, Inc.
1521 Concord Pike, Suite 301
Wilmington, DE 19803
(Serve via Certified Mail)

And

NEW ENGLAND CRYOGENIC
CENTER (NECC)
153 Needham Street
Newton, MA
(Serve via Certified Mail)

And

INNOVATIVE MEDICAL
CONSULTANTS, LLC
324 Countryside Drive
Broadview Hts, OH 44147
(Serve Nick B. Trankito
via Certified Mail)

DEFENDANTS

PARTIES

1. At all times relevant, Plaintiff, was a resident of and domiciled in the State of Kentucky.

2. At all times relevant, West Chester Hospital, LLC ("West Chester Hospital") was a limited liability company authorized to transact business and perform medical and treatment services in the State of Ohio and was operating under the trade name West Chester Hospital.

3. At all times relevant, Defendant UC Health Inc., was a duly licensed corporation which owned, operated and/or managed multiple hospitals including, but not limited to West Chester Hospital, and shared certain medical care, surgical care and services, and made income and profits from providing said services and also share liabilities for negligent care and treatment of patients including the Plaintiff herein including treatment at West Chester Hospital, LLC.

4. At all times relevant, TriHealth and Good Samaritan Hospital of Cincinnati were duly incorporated and authorized to do business in the State of Ohio providing medical and surgical care and treatment to patients like Plaintiff, with their principal offices in Hamilton County Ohio and are associated with or otherwise legally responsible in respondeat superior and/or agency for the conduct of defendants herein jointly and severally. Good Samaritan is a subsidiary of TriHealth.

5. Defendant the Center for Advanced Spine Technologies, Inc. is a corporation under the laws of Ohio and provides medical offices and is owned in whole or in part by Defendant Dr. Durrani. The agent for service of process is CT Corporation, 1300 East 9th Street, Suite 1010, Cleveland, OH 44114.

6. Defendant Dr. Durrani is/was licensed to practice medicine in the State of Ohio and the Commonwealth of Kentucky, has been indicted for Medicare fraud related to unnecessary surgeries, and performed the surgeries on Plaintiff involving PureGen and/or Infuse. Dr. Durrani can be served via e-mail at adurrani.yourspinedoctor@gmail.com.

7. Defendant Medtronic, Inc. ("Defendant Medtronic") is a Minnesota corporation, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432. Defendant Medtronic conducts business in the State of Ohio (hereinafter Product Defendants).

8. Defendant Medtronic Sofamor Danik USA, Inc. ("Defendant Medtronic Sofamor") is a Tennessee corporation, with its principal place of business at 1800 Pyramid Place, Memphis, Tennessee 38132. Defendant Medtronic Sofamor is a wholly owned subsidiary of Defendant Medtronic and conducts business in the State of Ohio and Kentucky (hereinafter Product Defendants).

9. Defendants Medtronic and Medtronic Sofamor (collectively "Product Defendants") are now and at all times relevant to this Complaint were, in the business of inventing, designing, manufacturing, creating, constructing, assembling, inspecting, and selling various types of medical drugs and devices, including spinal surgery drugs, solutions, hormones and devices, and specifically the INFUSE Bone Graft Bonegrowth Stimulator ("INFUSE").

10. At all times herein mentioned, "Product Defendants" and their aggregates, subsidiaries, corporates, limited liability companies, associates, and partners were the agent, servant, employee, assignee, permissive user, successor in interest or joint venture of each other, and were acting within the time, purpose or scope of such agency or employment or with permission actual and implied authority. And all acts or omissions alleged herein of each such "Product Defendants" were authorized, adopted, approved, or ratified by each of the other Product Defendants its agents, employees, officers, directors, contractors and subcontractors.

11. At all times herein mentioned, the officers and directors, employees, agents, contractors, subcontractors of the Product Defendants authorized and directed the production and/ or participated in the "off- label" promotion and use of Infuse® when they knew, or with the exercise of reasonable care should have known, of the

hazards and dangerous propensities of the "off- label" use of Infuse®, and thereby actively participated in the tortious, negligent, careless conduct which caused and contributed to and resulted in the physical injuries described herein.

12. At all times herein mentioned, each Product Defendant was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer of the other and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other, knowing that their collective conduct constituted a breach of duty owed to the Plaintiffs.

13. Defendant Alphatec Spine, Inc. is a corporation under the laws of California, and jointly developed and distributes PureGen in the State of Ohio. The agent for service of process is Ebun S. Garner, 5818 El Camino Real, Carlsbad, CA 92008.

14. Defendant Alphatec Holdings, Inc. is a holding corporation formed under the laws of Delaware with no operations separate from the holding of other companies which owns Alphatec Spine, Inc. The agent for service of process is Corporation Service Company, 2711 Centerville Road, Suite 400, Washington, DE 19808. (hereinafter Product Defendants).

15. Defendant Parcell Laboratories, LLC is organized under the laws of Delware and jointly developed PureGen. The agent for service of process is United States Corporation Agents, Inc., 1521 Concord Pike, Suite 301, Wilmington, DE 19803 (hereinafter Product Defendants).

16. Defendant New England Cryogenic Center (NECC) is located at 153 Needham Street, Building One, Newton, MA 02464 and whose service of registered agent is Joseph Rizza

and which business is wholly owned by Parcell Laboratories, LLC and manufactured and produced PureGen for the Co-Defendants herein named.

17. Defendant Innovative Medical Consultants, LLC is a corporation organized under the laws of Ohio, with its principle place of business located at 10963 Paddock Drive, Walton, KY 41094-9353. Innovative Medical Consultants, by and through employees, sales agents, and representatives market, distribute, sell and place into the stream of commerce the PureGen upon information and belief that was implanted into Plaintiff.

JURISDICTION AND VENUE

18. Jurisdiction and venue are proper in this Court since a substantial portion of the marketing, purchasing, storing, selling, and use of PureGen, INFUSE, surgery, diagnosis, failure to diagnose as well as many of the related acts or omissions, negligence, gross negligence, breach of the standard of care, unethical and improper use of non-FDA approved products, surgery and procedures giving rise to this lawsuit occurred in Butler County, Ohio.

19. This court has personal jurisdiction over the Medical Doctors and Hospital Defendants who are there employees and entities which employ them because, at all relevant times, they were residents of the State of Ohio, and/or tortious conduct occurred in the State of Ohio.

20. This court has personal jurisdiction over the Product Defendants because at all relevant times the product Defendants, their employees, agents, contractors, and subcontractors engaged in substantial business activities in the State of Ohio. At all relevant times, the Product Defendants transacted, solicited, and

conducted business in Ohio through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in Ohio.

21. Venue is proper in this Court as the primary conduct and tortious acts which gave rise to Plaintiffs' action occurred in Butler County, Ohio.

FACTUAL ALLEGATIONS

22. Plaintiff sought treatment with Dr. Abubaker Atiq Durrani in January 2010 because of intermittent pain in her back (hereinafter "Durrani").

23. Durrani recommended three surgical procedures on the first visit.

24. On October 1st, Durrani performed surgery at Good Samaritan Hospital to supposedly correct an L-5 Pars Defect.

25. Immediately following surgery, Plaintiff began experiencing back pain.

26. Plaintiff complained to Durrani about the new pain and Durrani informed her she would get relief after the second surgery.

27. On April 30, 2012, Durrani performed a lumbar fusion surgery on Plaintiff at West Chester Hospital.

28. Following this surgery Plaintiff continued to experience pain. Durrani told her to give it a year to heal.

29. Plaintiff continued to follow up with Durrani and complain of pain. Durrani scheduled a third surgery.

30. On October 29, 2012 Durrani performed a cervical fusion on Plaintiffs at West Chester Hospital.

31. Upon information and belief, Durrani used Infuse/BMP-2 in "off -label" manner and/or PureGen was used in her surgical procedure without Plaintiff's knowledge or consent, causing Plaintiff harm and permanent injury including swelling and closure of her airway.

32. Upon information and belief, Plaintiff, Delana Wheaton, had PureGen used upon her and, specifically,

    a. Puregen was implanted into the Plaintiff during a spine surgery without the informed consent of the Plaintiff;
    b. At the time of the surgery in which Puregen was used on the Plaintiff, Puregen was not FDA approved for use in the human spine;
    c. At the time of the surgery in which Puregen was used on the Plaintiff was not knowingly enrolled in a clinical trial;
    d. At the time of the surgery in which Puregen was used on the Plaintiff, Puregen was not subject to an Investigational New Drug (IND) application;

33. Furthermore Defendants had not applied for nor obtained approval by the FDA to conduct test of Puregen on individuals nor had obtained, filed and applied for a Biological License Application (BLA).

34. Upon information and belief, the surgeries performed by Durrani were medically unnecessary and improperly performed.

35. As a direct and proximate result of Plaintiff's surgeries, Durrani's negligence, and the Co-Defendants' negligence, improper and negligently credentialing or negligent retention as unethical use of non-FDA approved products. Plaintiff has suffered harm and damages in such amounts as the proof may show.

36. Plaintiff was not aware of Medtronic InfuselBMP-2 and/or PureGen product and the damages and injury that could be and was caused by its application until the recent publicity about Durrani and the Product Defendants.

COUNTS AGAINST WEST CHESTER HOSPITAL/UC HEALTH AND GOOD SAMARITAN

COUNT I: NEGLIGENCE

37. West Chester Hospital/UC Health AND Good Samaritan Hospital owed their patient, Plaintiff, through its agents and employees the duty to exercise the degree of skill, care, and diligence an ordinarily prudent health care provider would have exercised under like or similar circumstances.

38. West Chester Hospital/UC Health AND Good Samaritan Hospital acting through its agents and employees breached their duty by failing to exercise the requisite degree of skill, care and diligence that an ordinarily prudent health care provider would have exercised under same or similar circumstances through, among other things, negligent diagnosis, medical mismanagement and mistreatment of Plaintiff, including but not limited to improper selection for surgery, improper performance of the surgery, improper assistance during Plaintiff's surgeries and improper follow up care addressing a patient's concerns.

39. The agents and employees who deviated from the standard of care include nurses, physician assistants, residents and other hospital personnel who participated in Plaintiff's surgeries.

40. The management, employees, nurses, technicians, agents and all staff while in the course and scope of their employment and/or agency with West Chester Hospital/UC Health AND Good Samaritan Hospital either knew or should have known that the surgeries were not medically necessary based upon Durrani's known practices; the pre-op radiology; the pre-op evaluation and assessment; and the violation of their responsibility under the bylaws, rules, regulations and policies of West Chester Hospital/UC Health AND Good Samaritan Hospital.

41. As a direct and proximate result of the aforementioned negligence and deviation from the standard of care by the agents and employees of West Chester Hospital/UC Health AND Good Samaritan Hospital, Plaintiff sustained all damages requested in the prayer for relief.

COUNT II: NEGLIGENT CREDENTIALING, SUPERVISION, & RETENTION

42. As described in the Counts asserted directly against Durrani, the actions of Durrani with respect to Plaintiff constitute medical negligence, lack of informed consent, battery, and fraud.

43. West Chester Hospital/UC Health, AND Good Samaritan Hospital negligently credentialed, supervised, and retained Durrani as a credentialed physician by:

    a. Violating their Joint Commission on Accreditation of Healthcare Organizations (JCAHO) rules by allowing Durrani to repeatedly violate the West Chester Hospital/ UC Health bylaws with its full knowledge of the same;

b. Failing to adequately review, look into, and otherwise investigate Durrani's educational background, work history and peer reviews when he applied and reapplied for privileges at West Chester Hospital;

c. Ignoring complaints about Durrani's treatment of patients reported to it by staff, doctors, patients and others;

d. Ignoring information they knew or should have known pertaining to Durrani's previous privileged time at other Cincinnati area hospitals, including Children's Hospital, University Hospital, Deaconess Hospital, Good Samaritan Hospital and Christ Hospital.

44. As a direct and proximate result of the negligent credentialing, supervision, and retention of Durrani, Plaintiff sustained all damages stated herein and requested in the prayer for relief.

COUNT III PRODUCTS LIABILITY

45. At all times rhBMP-2/Infuse and PureGen were products as defined in O.R.C.§ 2307.71(A)(l2) and applicable law.

46. West Chester Hospital/UC Health AND Good Samaritan Hospital (aka supplier) its agents, employees, representatives, nurses, residents, doctors, contractor or subcontractors supplied Medtronic's (aka manufacturer) rhBMP-2/Infuse and/or PureGen for surgery performed by Durrani on Plaintiff.

47. West Chester Hospital/UC Health AND Good Samaritan Hospital, its agents, employees, representatives, nurses, residents, doctors, contractor or subcontractors did not adequately warn Plaintiff that rhBMP-2/Infuse and/or PureGen would be used without all FDA and manufacturer required components.

48. West Chester Hospital/UC Health AND Good Samaritan Hospital, its agents, employees, representatives, nurses, residents, doctors, contractor or subcontractors did not obtain informed consent from Plaintiff for the use of rhBMP-2/Infuse and/or PureGen, or warn of the potential danger and consequences of off-label use of the products without FDA and manufacturer requirements.

49. West Chester Hospital/UC Health AND Good Samaritan Hospital, its agents, employees, representatives, nurses, residents, doctors, contractor or subcontractors failed to provide any warning or instruction in regard to rhBMP-2/Infuse, and/or PureGen and failed to make sure any other party gave such warning or instruction.

50. West Chester Hospital/UC Health AND Good Samaritan Hospital, its agents, employees, representatives, nurses, residents, doctors, contractor or subcontractors substantially benefited financially by the use of the products as the products allowed for Defendant to charge more for the surgery.

51. Plaintiff suffered mental and physical harm due to West Chester Hospital/UC Health AND Good Samaritan Hospital, its agents, employees, representatives, nurses, residents, doctors, contractor or subcontractors' acts and omissions.

COUNT IV: CONSUMER PROTECTION ACT

52. Although the Ohio Consumer Sales Practices statutes O.R.C 1345.01 et seq. exempts physicians, a transaction between a hospital and a patient/consumer is not clearly exempted.

53. West Chester Hospital/UC Health's services and Good Samaritan Hospital rendered to Plaintiff constitute a "consumer transaction" as defined in ORC Section 1345.01(A).

54. West Chester Hospital/UC Health and Good Samaritan Hospital omitted, suppressed and concealed from Plaintiffs facts with the intent that Plaintiff's would rely on these omissions, suppressions and concealments as set forth herein.

55. West Chester Hospital/UC Health's and Good Samaritan Hospital misrepresentations, and its omissions, suppressions and concealments of fact, as described above, constituted unfair, deceptive and unconscionable acts and practices in violation of O.R.C 1345.02 and 1345.03 and Substantive Rules and case law.

56. West Chester Hospital/UC Health and Good Samaritan Hospitals were fully aware of its actions.

57. West Chester Hospital/UC Health and Good Samaritan Hospital were fully aware that Plaintiffs were induced by and relied upon West Chester Hospital/UC Health's and Good Samaritan Hospital's representations at the time they were engaged by Plaintiffs.

58. Had Plaintiffs been aware that West Chester Hospital/UC Health's and Good Samaritan Hospital's representations as set forth above were untrue, Plaintiffs would not have used the services of Defendants.

59. West Chester Hospital/UC Health and Good Samaritan Hospital, through its agency and employees knowingly committed the unfair, deceptive and/or unconscionable acts and practices described above.

60. West Chester Hospital/UC Health's and Good Samaritan Hospital's actions were not the result of any bona fide errors.

61. As a result of West Chester Hospital/UC Health's and Good Samaritan Hospital's unfair, deceptive and unconscionable acts and practices, Plaintiffs have suffered and continues to suffer damages, which include, but are not limited to the following:

a. Loss of money paid

b. Severe aggravation and inconveniences

c. Under O.R.C. 1345.01 Plaintiffs are entitled to:

i. An order requiring West Chester Hospital/UC Health and Good Samaritan Hospital restore to Plaintiffs all money received from Plaintiffs plus three times actual damages and/or actual/statutory damages for each violation;

ii. All incidental and consequential damages incurred by Plaintiffs;

iii. All reasonable attorneys' fees, witness fees, court costs and other fees incurred;

COUNT V: VICARIOUS LIABILITY AND AGENCY BY ESTOPPEL

62. West Chester Hospita/UC Health and Good Samaritan Hospital, its agents, employees, representatives, nurses, residents, doctors, contractors or subcontractors, Dr. Durrani, and

CAST are liable to Plaintiff pursuant to respondeat superior for the torts of its employees and/or agents.

63. West Chester Hospital/UC Health and Good Samaritan Hospital, its agents, employees, representatives, nurses, residents, doctors, and outside physicians, contractors or subcontractors, Dr. Durrani and CAST are liable to Plaintiff pursuant to the doctrine agency by estoppel.

64. West Chester Hospital/UC Health and Good Samaritan Hospital are liable for the negligence of its , its agents, employees, representatives, nurses, residents, doctors, contractors or subcontractors and physicians who are not its employees by virtue of Defendants' holding themselves out to the public as being a provider of medical services, and Plaintiffs had no knowledge, actual or implied, to the contrary, and Plaintiff relied upon the representation, advertising, and publicity offered by Defendants that the hospital would provide competent care but which representations were not true.

65. West Chester Hospital/UC Health and Good Samaritan Hospital are estopped from claiming its agents, employees, representatives, nurses, residents, doctors, contractors or subcontractors, the physicians and specifically Dr. Durrani are independent contractors and said Defendants are estopped from asserting other Defendants' responsibility for Plaintiff's injuries as a defense.

COUNTS AGAINST DR. DURRANI

COUNT I NEGLIGENCE

66. Defendants, Durrani, CAST, its employees and physicians owed his patient, Plaintiff, the duty to exercise the degree of skill, care, and diligence an ordinarily prudent health care provider would have exercised under like or similar circumstances.

67. Defendants, Durrani, CAST, its employees and physicians breached their duty by failing to exercise the requisite degree of skill, care and diligence that an ordinarily prudent health care provider would have exercised under same or similar circumstances through, among other things, negligent diagnosis, medical mismanagement and mistreatment of Plaintiff, including but not limited to improper selection for surgery, improper performance of the surgeries, and improper follow-up care addressing a patient's concerns and off-label use of rhBMP-2/Infuse.

68. As a direct and proximate result of the aforementioned negligence and deviation from the standard of care on the part of the Defendants, Durrani, CAST, its employees and physicians, the Plaintiff was injured in, on and about her body, both temporarily and permanently; incurred medical expenses, and will do so in the future; had her power to labor and earn money impaired, both past and future; was caused to suffer great pain, both mental and physical, past and future, all to her detriment and damage.

69. Plaintiff sustained all damage stated herein and/or requested in the prayer for relief.

COUNT II BATERY

70. Durrani, CAST, its employees and physicians committed battery against Plaintiff by performing surgeries that were unnecessary, contraindicated for Plaintiffs medical condition, and for which he did not properly obtain informed consent, inter alia, by using rhBMP-2/Infuse and/or PureGen in ways and for surgeries not approved by the FDA and medical community, and by the failure to provide this information to Plaintiff.

71. Plaintiff would not have agreed to the surgeries if she knew the surgeries were unnecessary, not approved by the FDA, and not indicated.

72. As a direct and proximate result of the aforementioned battery by Durrani, CAST, its employees and physicians, Plaintiff sustained all damages stated herein and requested in the prayer for relief.

COUNT III: LACK OF INFORMED CONSENT

73. The informed consent forms from Durrani, CAST, West Chester Hospital and Good Samaritan, employees and physicians, which they required Plaintiff to sign, failed to fully cover all the information necessary and required for the procedures and surgical procedures performed by Durrani. Durrani, CAST, West Chester Hospital, Good Samaritan their employees and physicians each required an informed consent release.

74. In addition, no one verbally informed Plaintiff of the information and risks required for informed consent at the time of or before the Plaintiff s surgeries.

75. Durrani, CAST, West Chester Hospital and Good Samaritan, their employees and physicians failed to inform Plaintiff of material risks and dangers inherent or potentially involved with her surgeries and procedures.

76. Plaintiff subsequently developed severe and grievous injuries as a direct and proximate result of lack of informed consent.

77. Had the Plaintiff been properly informed of the need or lack of need for surgeries and other procedures and the risks of the procedures, Plaintiff would not have undergone the surgeries or procedures.

COUNT IV: FRAUD

78. Durrani, CAST, its employees and physicians made material, false representations to Plaintiff and her insurance company related to Plaintiffs treatment including: stating the surgeries were necessary, that Durrani "could fix" Plaintiff, that more conservative treatment was unnecessary and futile, that the surgeries would be simple or was "no big deal", that Plaintiff would be walking normally within days after each surgery, that the procedures were medically necessary and accurately reported on the billing to the insurance company, that the surgeries were successful, and that Plaintiff was medically stable and ready to be discharged.

79. Durrani, CAST, its employees and physicians also concealed the potential use of rhBMP-2/Infuse in Plaintiff's surgeries when he had a duty to disclose to Plaintiff of his planned use of the same.

80. These misrepresentations and/or concealments were material to Plaintiff because they directly induced the Plaintiff to undergo her surgeries.

81. Durrani, CAST, its employees and physicians knew or should have known such representations were false, and/or made the misrepresentations with utter disregard and recklessness as to their truth that knowledge of their falsity may be inferred.

82. Durrani, CAST, its employees and physicians made the misrepresentations before, during, and after the surgeries, with the intent of misleading Plaintiff and her insurance company into relying upon them. Specifically, the misrepresentations were made to induce payment by the insurance company, without which Durrani, CAST, its employees and physicians would not have performed the surgeries, and to induce Plaintiff to undergo the surgeries without regard to medical necessity and only for the purpose of receiving payment.

83. The misrepresentations and/or concealments were made during the Plaintiffs office visits at Durrani's CAST offices and/or at West Chester Hospital/UC Health and/or Good Samaritan.

84. Plaintiff was justified in her reliance on the misrepresentations because a patient has a right to trust their doctor and that the facility is overseeing the doctor to ensure the patients of that doctor can trust the facility.

85. As a direct and proximate result of the aforementioned fraud, Plaintiff did undergo surgery, which was paid for in whole or in part by her insurance company, and suffered all damages requested in the prayer for relief.

COUNT V: DURRANI'S USE OF INFUSE and/ or PUREGEN

86. Durrani oftentimes used INFUSE BMP-2 "off-label", or PureGen when performing surgeries.

87. Durrani was a consultant for Medtronic and he owned an interest in PureGen.

88. Defendants, jointly and severally, did not inform Plaintiff of Durrani's financial interest, conflicts of interest or consulting arrangement with Medtronic and PureGen.

89. Medtronic, provided in writing to Durrani and CAST the approved uses for rhBMP-2/Infuse, the substance also referred to as Infuse, which is a bone morphogenic protein, used as an artificial substitute for bone grafting in spine surgeries.

90. RhBMP-2/Infuse is not approved by the Food and Drug Administration for use in the cervical and thoracic spine; PureGen is not approved for any use by the FDA.

91. RhBMP-2/Infuse is approved by the FDA for a limited procedure, performed on a limited area of the spine, using specific components. Specifically, the FDA approved Infuse for one procedure in the lumbar spine: Anterior Lumbar Interbody Fusion ("AUF" or "Anterior" approach); and only in one area of the spine: L4 to S1; and only when used in conjunction with FDA-Approved Components: LT-CAGE Lumbar Tapered Fusion Device Component ("LT-CAGE")

92. Use of Infuse in cervical or thoracic surgery, or use through the back (posterior), or side (lateral), or on areas of the spine outside of the L4-S1 region (e.g., the cervical or thoracic spine), or using components other than or in addition to the LT-CAGE is

not approved by the FDA, and thus such procedures and/or use of non-FDA approved componentry is termed "off-label."

93. Puregen and off-label use of Infuse frequently causes excessive or uncontrolled bone growth on or around the spinal cord and directly causes nerves to be compressed by such excessive bone growth, with the result that patients can experience among other adverse events, intractable pain, paralysis, spasms and cramps in the limbs.

94. The product packaging for rhBMP-2/Infuse indicates it causes an increased risk of cancer four (4) times greater than other bone graft alternatives.

95. Durrani, and CAST staff and employees, and West Chester, UC Health and Good Samaritan personnel did not disclose to Plaintiff their intent to authorize, promote and permit use of PureGen and/or rhBMP-2/Infuse, and further, did not disclose their intent to use rhBMP-2/Infuse in a way not approved by the FDA.

96. Upon information and belief, Durrani and CAST, its employees, agents, and physicians used PureGen and/or rhBMP-2/Infuse on Plaintiff in manners not approved by the FDA.

97. Defendants, jointly and severally, did not inform Plaintiff that Durrani and CAST, its employees and physicians used PureGen and/or rhBMP-2/Infuse in her surgeries.

98. Plaintiff would not have allowed PureGen and/or rhBMP-2/Infuse to be used by Durrani and CAST employees and physicians in her surgeries in a manner that was not approved by the FDA had she been properly informed and had she been warned of the known side effects of use of the PureGen and/or rhBMP-2/Infuse.

99. Plaintiff did not sign any consent agreement in which she was fully advised to the use of PureGen and/or rhBMP-2/Infuse in her body and was not informed of the risks by

Durrani, CAST staff and employees, or any West Chester UC Health personnel or Good Samaritan Personnel.

100. Any written informed consent, if any such form exist, provided her by Durrani, CAST, its employees and physicians and West Chester UC Health and Good Samaritan, its employees, nurses and physicians signed by Plaintiff lacked the disclosure of PureGen and/or rhBMP-2/Infuse's use in her procedure and lacked disclosure of neck swelling, cancer, sterility, excessive bone growth and other adverse consequences caused by its use.

101. Plaintiff never received a verbal disclosure of PureGen and/or rhBMP-2/Infuse from Durrani, CAST staff and employees, or any West Chester UC Health personnel or Good Samaritan, employees, physicians, agents, contractors, subcontractors or personnel.

102. Medtronics label for approved use of Infuse required at least six (6) months of non-operative treatment prior to use of rhBMP-2/Infuse, but which requirement Durrani, CAST, its employees, agents and physicians ignored and disregarded to the detriment and damages of Plaintiff.

103. Durrani, CAST, its employees and physicians regularly used rhBMP-2/Infuse without this six (6) month non- operative treatment.

104. The FDA approved required rhBMP-2/Infuse be used in conjunction with a metal LT cage at the L-5 to S-1 only but which labeling and use was disregarded by all Defendants and for which all Defendants are liable, jointly and severally.

105. Durrani, CAST employees and physicians regularly used r h BMP-2/Infuse without a proper LT cage in his surgeries and which procedures and use all Defendants knew or should have known was "off label" and which use directly and causally caused to Plaintiff damages and which damages all Defendants are liable, jointly and severally.

106. Durrani, CAST employees and physicians regularly used PureGen without proper FDA approval, which use directly and causally caused to Plaintiff damages and which damages all Defendants are liable, jointly and severally.

COUNT VI: SPOLIATION OF EVIDENCE

107. Dr. Durrani willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiff's records, emails, billing records, paperwork and related evidence.

108. Dr. Durrani spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.

109. Dr. Durrani's conduct was designed to disrupt Plaintiff's potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

COUNTS AGAINST CAST

COUNT I: VICARIOUS LIABILITY

110. At all times relevant, Defendant Durrani was an agent, and/or employee of CAST.

111. Durrani is in fact believed to be the owner of CAST.

112. Defendant Durrani and the other CAST employees and physicians were performing within the scope of their employment with CAST during the care and treatment of Plaintiff.

113. Defendant CAST is responsible for harm caused by acts of its employees for conduct that was within the scope of employment under the theory of respondeat superior.

114. Defendant CAST is vicariously liable for the acts of Defendant Durrani as alleged in this Complaint including all of the counts asserted against Durrani directly.

115. As a direct and proximate result of Defendant CAST, its agents, employees and physicians' acts and omissions, Plaintiff sustained all damages stated herein and requested in the prayer for relief.

COUNT II: NEGLIGENT HIRING, RETENTION & SUPERVISION CREDENTIALING

116. CAST provided Durrani, inter alia, financial support, control, medical facilities, billing and insurance payment support, staff support, medicines, and tangible items for use on patients.

117. CAST and Durrani participated in experiments using rhBMP-2/Infuse bone graft on patients, including Plaintiff, without obtaining proper informed consent thereby causing harm to Plaintiff.

118. CAST breached its duty to Plaintiff, inter alia, by not supervising or controlling the actions of Durrani, the doctors, nurses and staff and those with privileges during the medical treatment of Plaintiff at CAST.

119. The Safe Medical Device Act required entities such as CAST to report serious injuries, serious illnesses, and deaths related to failed medical devices to the FDA and the manufacturer; this was never done.

120. Such disregard for and violations of federal law represents strong evidence that CAST negligently hired, retained and supervised Durrani.

121. As a direct and proximate result of the acts and omissions herein described, including but not limited to failure to properly supervise medical treatment by Durrani, Plaintiff sustained all damages stated herein and as requested in the prayer for relief.

COUNT III: FRAUD

122. CAST sent invoices for payment to Plaintiff at her home following her surgeries at West Chester Hospital/UC Health and Good Samaritan.

123. These bills constituted affirmative representations by CAST, its employees and physicians that the charges related to Plaintiffs surgeries were medically appropriate and properly documented.

124. The bills were sent with the knowledge of CAST, its employees and physicians that in fact Plaintiff's surgeries were not appropriately billed and documented and that the services rendered at West Chester Hospital/UC Health and/or Good Samaritan associated with Durrani were not appropriate.

125. The bills sent by CAST, its employees and physicians to Plaintiff falsely represented that Plaintiff's surgeries were appropriately indicated, performed and medically necessary in contra-indication of the standard of care.

126. Plaintiff relied on the facility holding Durrani out as a surgeon and allowing him to perform surgeries at its health care facility as assurance the facility was overseeing Durrani, vouching for his surgical abilities, and further was appropriately billing Plaintiff for CAST's services in association with Durrani's surgery.

127. As a direct and proximate result of this reliance on the billing of CAST, Plaintiff incurred medical bills that she otherwise would not have incurred.

128. CAST also either concealed from Plaintiff that they knew about Durrani including that rhBMP-2/Infuse and/or PureGen would be used in Plaintiff's surgeries, or misrepresented to Plaintiff the nature of the surgeries, and the particular risks that were involved therein.

129. CAST, its employees and physicians' concealments and misrepresentations regarding rhBMP-2/Infuse and/or PureGen and the nature and risks of Plaintiff s surgeries were material facts. Because of its superior position and professional role as a medical service provider, CAST, it's employees and physicians had a duty to disclose these material facts to Plaintiff and a duty to refrain from misrepresenting such material facts to Plaintiff.

130. CAST, its employees and physicians intentionally concealed and/or misrepresented said material facts with the intent to defraud Plaintiff in order to induce Plaintiff to undergo the surgeries, and thereby profited from the surgeries and procedures Durrani performed on Plaintiff at West Chester Hospital, UC Health and/or Good Samaritan.

131. Plaintiff sustained all damages stated herein and/or requested in the prayer for relief.

COUNT IV: OHIO CONSUMER SALES PROTECTION ACT

132. Although the Ohio Consumer Sales Protection statutes O.R.C 1345.01 et seq. exempts physicians, a transaction between a hospital and a patient/consumer is not clearly exempted.

133. CAST's services rendered to Plaintiff constitute a "consumer transaction" as defined in ORC Section 1345.01(A).

134. CAST omitted, suppressed and concealed from Plaintiff facts with the intent that Plaintiff would rely on these omissions, suppressions and concealments as set forth herein.

135. CAST's misrepresentations, and its omissions, suppressions and concealments of fact, as described above, constituted unfair, deceptive and unconscionable acts and practices in violation of O.R.C 1345.02 and 1345.03 and to Substantive Rules and case law.

136. CAST was fully aware of its actions.

137. CAST was fully aware that Plaintiff was induced by and relied upon CAST's representations at the time CAST was engaged by Plaintiff.

138. Had Plaintiff been aware that CAST's representations as set forth above were untrue, Plaintiff would not have used the services of Defendants.

139. CAST, through its agency and employees knowingly committed the unfair, deceptive and/or unconscionable acts and practices described above.

140. CAST's actions were not the result of any bona fide errors.

141. As a result of CAST's unfair, deceptive and unconscionable acts and practices, Plaintiffs have suffered and continues to suffer damages, which include, but are not limited to the following:

a. Loss of money paid

b. Severe aggravation and inconveniences

c. Under O.R.C. 1345.01 Plaintiffs are entitled to:

i. An order requiring that CAST restore to Plaintiffs all money received from Plaintiffs plus three times actual damages and/or actual/statutory damages for each violation;

ii. All incidental and consequential damages incurred by Plaintiffs;

iii. All reasonable attorneys' fees, witness fees, court costs and other fees incurred;

COUNT V: SPOLIATION OF EVIDENCE

142. CAST, through its agents and employees, willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiff's records, emails, billing records, paperwork and related evidence.

143. CAST, through its agents and employees, spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.

144. CAST's conduct was designed to disrupt Plaintiff's potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

COUNT VI: AGENCY BY ESTOPPEL

145. CAST, its agents, employees, representatives, nurses, residents, doctors, contractors or subcontractors, Dr. Durrani, and CAST are liable to Plaintiff pursuant to respondeat superior for the torts of its employees and/or agents.

146. CAST, its agents, employees, representatives, nurses, residents, doctors, and outside physicians, contractors or subcontractors, Dr. Durrani and CAST are liable to Plaintiff pursuant to the doctrine agency by estoppel.

147. CAST is liable for the negligence of its agents, employees, representatives, nurses, residents, doctors, contractors or subcontractors and physicians who are not its employees by virtue of Defendants' holding themselves out to the public as being a provider of medical services, and Plaintiffs had no knowledge actual or implied to the contrary, and Plaintiff relied upon the representation, advertising, and publicity offered by Defendants that the hospital would provide competent care but which representations were not true.

148. CAST is estopped from claiming its agents, employees, representatives, nurses, residents, doctors, contractors or subcontractors, the physicians and specifically Dr. Durrani are independent contractors and said CAST is estopped from asserting other Defendants' responsibility for Plaintiff's injuries as a defense.

COUNTS AGAINST MEDTRONICS /PRODUCT DEFENDANTS

COUNT I: NEGLIGENCE

149. The Product Defendants had a duty to exercise reasonable care in the design, testing, manufacture, warning, marketing, distribution, and/or sale of rhBMP-2/Infuse ,including a duty to ensure that it did not cause injury to individuals in which it was placed and or injected or applied..

150. The Product Defendants owed a duty of reasonable care to Plaintiff and were required to protect her against the foreseeable risk of harm posed by the off-label use of rhBMP-2/Infuse.

151. The Product Defendants breached their duty of care owed to Plaintiff to protect her from an unreasonable risk of harm in that they negligently and carelessly, researched, tested, manufactured, designed, developed, distributed, advertised,

marketed, inspected, configured, failed to warn and/or sold rhBMP-2/Infuse to physicians and hospitals for use in patients like Plaintiff.

152. The Product Defendants were negligent by, *inter alia:*

a. engaging in the illegal off-label promotion of rhBMP-2/Infuse by recommending to physicians, including Plaintiff's physicians, and instructing them to use it in procedures for which it had not been approved;

b. instructing, promoting and directing the use of rhBMP-2/Infuse in procedures that had not been approved by the FDA;

c. failing to disclosure to physicians that the off-label use of rhBMP-2/Infuse can result in serious side effects;

d. failing to fully disclose the results of the testing and other information in its possession regarding the possible adverse reactions associated with the off-label use of rhBMP-2/Infuse;

e. representing that the off-label use of the rhBMP-2/Infuse was safe when, in fact, it was unsafe;

f. promoting rhBMP-2/Infuse beyond the narrow and limited uses for which it was approved;

g. failing to adequately warn the medical community, the general public, Plaintiff's physicians, and Plaintiffs of the dangers, contraindications, and side effects from the off-label use of rhBMP-2/Infuse; and

h. failing to act as a reasonably prudent drug manufacturer by, *inter alia,* commissioning studies which misrepresented the risks associated with off-label use of rhBMP-2/Infuse and compensating the authors of the above studies monetarily for their opinions.

153. The rhBMP-2/Infuse drug implanted, applied, injected, placed into Plaintiff was defective when it left the hands of the Product Defendants.

154. The Product Defendants further negligently failed to warn or alert Plaintiff of the dangers and hazards associated with the off-label use of rhBMP-2/Infuse

155. The Product Defendants knew or should have known that the off-label use of rhBMP-2/Infuse was unreasonably dangerous and harmful to persons who would have it used on them and which use was foreseeable and intended by Product Defendant.

156. As a direct and proximate result of the Product Defendants' negligence, carelessness and tortious conduct and violation of FDA Rules and Regulations. Plaintiff has suffered severe and permanent injuries as described above. These injuries have caused her to incur medical, hospital, and drug expenses and, due to the permanent nature of the injuries, will cause her to incur medical, hospital, and drug expenses in the future and for which damages Defendants are jointly and severally liable to Plaintiff.

157. As a direct and proximate result of the Product Defendants' negligence, carelessness and tortious conduct and violation of FDA Rules and Regulations. Plaintiff has suffered severe pain, mental anguish, loss of enjoyment of life, and permanent loss of earning capacity, and due to the permanent nature of the injuries will continue to suffer from severe pain, mental anguish, loss of enjoyment of life, and loss of income in the future and for which damages Defendants are jointly and severally liable to Plaintiff.

COUNT II: PRODUCTS LIABILITY

158. The Product Defendants in their regular course of business, designed, tested, manufactured, distributed, sold, and/or placed rhBMP-2/Infuse into interstate commerce.

159. The off-label use of rhBMP-2/Infuse in Plaintiff was defective, unsafe, and ineffective, and the Product Defendants knew or should have known that it was unsafe and ineffective when used in an off-label manner as promoted, instructed, and supplied by the Product Defendants, and as utilized in Plaintiff's surgery.

160. The Product Defendants promoted the off-label use of rhBMP-2/Infuse with the knowledge of its risk to patients.

161. The Product Defendants:

a. knew that rhBMP-2/Infuse, when used off-label in the manner described above and as promoted and instructed by the Product Defendants, was defective and dangerous in the manner described above;

b. knew that, because said use was dangerous and defective when so used off-label, the product could not safely be used for the purpose intended;

c. acted in a despicable manner and in conscious disregard of the safety of the public, including the safety of Plaintiff Delana Wheaton, when it placed the product on the market without warning of the defect, despite knowing that said product when used off-label was defective and dangerous; and

d. knew when so placed, applied, injected in Plaintiff that it would be used without adequate inspection and review by the FDA for defects but despite said knowledge promoted and marketed its use.

162. By placing said product on the market and promoting said off-label use, the Product Defendants impliedly represented it was safe for the purpose intended, and intended that physicians should rely on their misrepresentations. In doing the things aforementioned, the Product Defendants are guilty of malice, oppression, and fraud, and Plaintiff is therefore entitled to exemplary or punitive damages in a sum according to proof at trial.

163. rhBMP-2/Infuse, when used off-label, was designed in a materially defective manner.

164. The off-label use of rhBMP-2/Infuse was not only reasonably foreseeable, but explicitly intended by the promotion and marketing by the Product Defendants.

165. The Product Defendants knew, or in the exercise of reasonable diligence, should have known of the risk of injury to the Plaintiff, and others like her, from the use of the product.

166. As a direct and proximate result of the Product Defendants defective product, Plaintiff has suffered severe and permanent injuries and damages.

167. The Product Defendants breached the implied warranties of merchantability and fitness because rhBMP-2/Infuse is unsafe for the promoted uses, is not merchantable, is unfit for its promoted use when sold, is unfit for the purpose for which it was sold, and/or is not adequately packaged and labeled, and did not reasonably conform to the promises or affirmations of fact made by the Product Defendants.

168. The actions of the Product Defendants, their agents, servants, and/or employees were wanton, grossly negligent, and reckless and demonstrated a complete disregard and reckless indifference to the safety and welfare of Plaintiff in particular, and to the public generally, in that the Product Defendants did willfully and knowingly promote the off-label use of rhBMP-2/Infuse with the specific knowledge regarding its efficacy, risks, and side effects.

169. Despite their specific knowledge regarding risks as set forth above, the Product Defendants deliberately recommended the off-label use of rhBMP-2/Infuse and promoted it to be safe and effective.

170. The Product Defendants' conduct was malicious, fraudulent, and oppressive toward Plaintiff in particular and the public generally, and the Product Defendants conducted themselves in a willful, wanton, and reckless manner.

171. In doing the things aforementioned, the Product Defendants are guilty of malice, oppression, and fraud, and Plaintiff is therefore entitled to recovery of exemplary or punitive damages in a sum according to proof at trial.

COUNTS AGAINST PUREGEN DEFENDANTS

COUNT I: NEGLIGENCE, RECKLESSNESS AND WANTON CONDUCT

172. Upon information and belief PureGen was used in the surgeries performed on Plaintiff.

173. Defendants Alphatec Spine, Inc, Alphatec Holdings, Inc, Parcell Laboratories, New England Cryogenic Center, and Innovative Medical Consultants are collectively referred to herein as "PureGen Defendants"

174. Defendants Alphatec and Parcell co-developed the product "PureGen", and both expected PureGen would be initially limited in application.

175. PureGen is produced and distributed by Alphatec Spine, LLC, a division of Alphatec Holdings, Inc.

176. PureGen is a biologics device or product. According to the Public Health Service Act, a valid biologics license is also required to introduce a biologics device to the market.

177. Alphatec Spine did not acquire a valid biologics license to enter a biological product into interstate commerce, in violation of 21 U.S.C. 355(a); 42 U.S.C. 262(a).

178. Dr. Atiq Abubakar Durrani, CAST, its employees and physicians used the product PureGen in its patients and specifically Plaintiff

179. PureGen Defendants knowingly provided PureGen to Dr. Durrani, CAST and its employees and physicians.

180. On information and belief, a representative from Alphatec Spine was in the operating room during medical procedures.

181. Durrani, CAST and its employees and physicians acted as consultants for PureGen Defendants.

182. Durrani, CAST and its employees and physicians performed unnecessary surgeries using PureGen on patients and Plaintiff herein.

183. The Defendants concealed from Plaintiff the serious medical risks and complications to increase profits, specifically concealing that PureGen would be used, omitting that the effectiveness and safety of PureGen had not been determined at that time, and concealed risk factors known by PureGen Defendants at that time.

184. The Defendants, together and individually knew that the surgeries using PureGen were not approved by the FDA (unlicensed) and were being performed without the consent and knowledge of the patients.

185. PureGen Defendants designed, tested, manufactured, marketed, sold, and/or distributed PureGen.

186. At all relevant times herein, PureGen Defendants had a duty to safely and properly design, manufacture, test, inspect, package, label, distribute, market, sell, examine,

maintain, supply, provide proper warnings, and prepare for use and sale these products, as well as comply all applicable laws and regulations.

187. PureGen Defendants negligently, recklessly, and/or wantonly breached their duty in one or more ways set forth herein.

188. PureGen Defendants' breaches proximately caused Plaintiff's injuries and damages.

189. At the time PureGen was, upon information and belief, implanted into the Plaintiff, "PureGen" remained unregulated, and was not approved to be sold or used in humans whatsoever.

190. Natural bone allograft and autograft substitutes, such as PureGen, frequently cause excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs, difficulty breathing and swallowing.

191. Following the surgery, Plaintiff suffered some of these side effects.

192. Plaintiff was misled by PureGen Defendants concerning the extent, nature and duration of the surgery that was to be performed.

193. PureGen Defendants affirmatively promoted and sold PureGen without a license, in violation of state and federal law.

194. Safe, reasonable and/or adequate warnings and instructions for use of PureGen were not provided to the Plaintiff by the PureGen Defendants.

195. As a direct and proximate result of PureGen Defendants' conduct and violations of the law, Plaintiff suffered harm as alleged in this Complaint.

COUNT II: PRODUCT LIABILITY

196. PureGen Defendants designed, tested, manufactured, marketed, sold, and/or distributed PureGen with the intention that it be used in spine surgeries such as were performed on the Plaintiff.

197. The defective condition of PureGen Defendants' product rendered it unreasonably dangerous to the Plaintiffs as it was expected to be used.

198. The defective and unreasonably dangerous condition of PureGen Defendants' product proximately caused the Plaintiff's injuries and damages, which were known, or should have been known through the exercise of ordinary care, by Defendants to be causally associated with such defects.

199. PureGen was defectively designed and manufactured at the time that it left the PureGen Defendants' control and was placed into the stream of commerce in Ohio. The unlicensed and unapproved drug/biologic reached Plaintiff without a substantial change in the condition in which it was sold.

200. The PureGen product was unreasonably dangerous in that it was unsafe when used as it was promoted by PureGen Defendants for use in spine surgeries.

201. The PureGen product failed to perform as safely as an ordinary consumer would expect.

202. Plaintiff's physicians used the PureGen product in the way PureGen Defendants intended and promoted it to be used.

203. Plaintiff could not have discovered any defect in the PureGen product through the exercise of ordinary care.

204. PureGen Defendants' unreasonably-dangerous and/or defective manufacture of PureGen was the direct, legal and proximate cause of Plaintiff's injuries and damages including, but not limited to, medical hospital expenses and lost wages.

205. As a direct and proximate result of the acts, omissions and/or dangerous conditions described herein, Plaintiff has sustained serious injuries of a personal and pecuniary nature.

206. PureGen Defendants designed, tested, manufactured, marketed, sold and/or distributed PureGen with the intention that it be used in unlicensed, experimental, research, non-FDA approved, and/or secret spinal fusion surgical applications, such as the Plaintiff's.

207. PureGen was defective because PureGen Defendants failed to adequately warn ordinary consumers regarding its use, and the product failed to contain adequate warnings and/or instructions.

208. PureGen Defendants knew, or should have known in light of reasonable available information, that the ordinary consumer, such as the Plaintiff, would not realize the dangerous and defective condition of its product when used in these unlicensed ways.

209. PureGen Defendants' failed to communicate sufficient information, including adequate warnings and/or instructions, to Plaintiff regarding the dangers of PureGen of which they knew or should have known, taking into account the characteristics of, and the ordinary knowledge it has.

210. The defective condition of PureGen Defendants' product rendered it unreasonably dangerous to the Plaintiff.

211. The defective and unreasonably dangerous condition of PureGen Defendants' product, PureGen proximately caused the Plaintiff's injuries, harm or damages.

212. PureGen Defendants further impliedly warranted that PureGen was fit for the particular purpose of treating the Plaintiff.

213. PureGen Defendants breached implied warranties of merchantability and fitness for a particular purpose when its product was sold to the Plaintiff, as PureGen was defective, unmerchantable, and unfit for ordinary use when sold, and unfit for the particular purpose for which it was sold, subjecting the Plaintiff to severe and permanent injuries.

214. As a result of the manufacturer's breach of the implied warranties of merchantability and fitness for a particular purpose, Plaintiff has sustained, and will continue to sustain, injuries and damages.

PLAINTIFF'S DAMAGES

215. As a direct and proximate result of the joint and several conduct of Defendants herein, Plaintiff has suffered severe and permanent injuries as described above. These injuries have caused her to incur medical, hospital, and drug expenses and, due to the permanent nature of the injuries, will cause her to incur medical, hospital, and drug expenses in the future.

216. As a further direct and proximate result of the joint and several conduct of Defendants, Plaintiff has suffered severe pain, mental anguish, loss of enjoyment of life, and permanent loss of earning capacity, and due to the permanent nature of the injuries will continue to suffer from severe pain, mental anguish, loss of enjoyment of life, and loss of income in the future.

217. As a direct and proximate result of the aforementioned joint and several conduct of the Defendants, Plaintiff was injured in, on and about her body, both temporarily and permanently; incurred medical expenses, and will do so in the

future; had her power to labor and earn money impaired, both past and future; was caused to suffer great pain, both mental and physical, past and future, all to her detriment and damage.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, in excess of $25,000, plus attorney fees, costs, punitive damages, pre-judgment interest and for any and all other relief Plaintiff may be entitled to at law or equity.

Jury Demand

Plaintiff herein demands a Trial by Jury.

Respectfully submitted,

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